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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,290	03/24/2004	Cindra A. Widrig Opalsky	215105.00608	3910
27160 7590 08/22/2007 PATENT ADMINISTRATOR KATTEN MUCHIN ROSENMAN LLP 1025 THOMAS JEFFERSON STREET, N.W. EAST LOBBY: SUITE 700 WASHINGTON, DC 20007-5201			EXAMINER ALEXANDER, LYLE	
			ART UNIT 1743	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/807,290	Applicant(s) OPALSKY ET AL.	
	Examiner Lyle A. Alexander	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 90-167 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 90-167 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90-167 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 90 step (d) is not clear if the sample is metered into another chamber. Step (f) is not clear if the sample is moved to a new location positioned near the sensor by the pump or if the sample remains at the position where it was mixed with the reagent. Clarification could be achieved by Applicants numbering the various chambers (e.g. a first holding chamber..., a second overflow chamber ..., a third holding chamber ..., a fourth analysis chamber ... etc.). Claim 167 is also unclear to locations the metering locations of the sample and could also be clarified by numbering the various chambers as suggested above.

Claims 108 and 119 do not appear to further limit the method of claim 90 because it is directed to the method of making the holding chamber and should be deleted. Additionally, claim 119 is further improper because this claim could be of identical scope to claim 108 if the at least one surface is the holding chamber.

Claim 120 does not appear to further limit the method of claim 90 because it is directed to the shape/size of the apparatus.

Claim 121 is not clear if it is a method or structural limitation. The claim could be clarified if "adding a predetermined amount or reagent in the holding chamber" were claimed.

Claim 127 is unclear what method steps are intended by "the reagent included solubility enhancing components". Does Applicant intend addition of a surfactant ?

Claims 128-129 are not clear how this further limits the method of claim 90 and what is the electrochemical species.

Claim 130 is not clear how this further limits the method of claim 90 and the locations where the enzyme substrates are located.

Claim 133 is not clear how this further limits the method of claim 90, what the matrix is or how dissolution is promoted.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 90-167 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-107 and claims 1-47 of U.S. Patent No. 6,750,053 and 6,438,498 respectively. Although the conflicting claims are not identical, they are not patentably distinct from each other because are directed to placing the sample in a holding chamber, metering off the overflow from the holding chamber, metering the sample to a an analysis location, mixing the sample with a reagent, etc. The 6,750,053 patent is related to the instant application as a continuation and not as a divisional which is why the patent is available for this double patenting rejection (e.g. there was no restriction requirement made in the patent).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States:

Claims 90-104,107,109-118,123,127,131-135, 144-145 and 167 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Besemer et al. (USP 5,104,813).

Besemer et al. teach a method of detecting a reaction product where a sample is introduced into a holding chamber, excess sample removed, reagents added and

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mixed. The resultant reaction is detection and the analyte of interest is quantified.

There is a stop junction to control the fluid flow and a hydrophobic region.

Claims 90-105,107,109-118,123,127,131-135, 144-145 and 167 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Handique et al. (USP 6,130,098).

Handique et al. (USP 6,130,098) teach a method of detecting a reaction product where a sample is introduced into a holding chamber, excess sample removed, and reagents added and mixed. The resultant reaction is detection and the analyte of interest is quantified. There is a stop junction to control the fluid flow and a hydrophobic region. Handique et al. (USP 6,130,098) additionally teaches in columns 17-18 lines 63-68 respectively silicon dioxide surface and in column 26 line 20 teach a digestion buffer.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 124-126, 136-143 and 146-166 are rejected under 35 U.S.C. 103(a) as being unpatentable over Besemer et al. (USP 5,104,813) or by Handique et al. (USP 6,130,098).

See Besemer et al. (USP 5,104,813) and by Handique et al. (USP 6,130,098) *supra*.

These references are silent to the claimed reagent to perform agglutination assays.

Applicants' section 3 "BACKGROUND OF THE INVENTION" in the original disclosure teaches multiple references outlining the claimed reagent used for agglutination assays.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one

that has well known and expected results. The reagents chosen for an assay are a result effective variable with the well-known and expected result of testing for the analyte of interest. Agglutination testing of blood is desirable to determine the bleeding risk of a surgical patient.

It would have been within the skill of the art to modify Besemer et al. (USP 5,104,813) or by Handique et al. (USP 6,130,098) and use the claimed reagents above to achieve the well known and expected results of agglutination analysis because this is a necessary test for preoperative patients and also as the selection of a result effective variable.

#### ***Election/Restrictions***

Applicant's election without traverse of claims 90-167 in the reply filed on 6/8/07 is acknowledged.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lyle A Alexander  
Primary Examiner  
Art Unit 1743

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